UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORK

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UNITED STATE OF AMERICA Plaintiff

V

Case No. 22-CV-1159 (Vitaliano, J.)(Levy, M.J.)

Date: April 11, 2024. FILED

Ş Apr 12, 2024, 4:02 PM ANDREW SINCLAIR / B4B EARTH TEA in the Clerk's Office LLC / B4B CORP U.S. District Court, Defendant EDNY, Brooklyn Pro Se Office via

Box.com

DEFENDANT RESPONSE TO PLAINTIFF MOTION TO DISMISS

Plaintiff United States of America has conducted Abuse of Process, where the plaintiff premeditated this case to achieve malicious prosecution. This lawsuit was filed with no evidence, no testing, no trial, no research or no questioning to Defendant about the product in question. I request that sovereign immunity be denied and this motion be dismissed. I asked that the Plaintiff is held accountable for attempting wrongful conviction and monetary pain and suffering be granted for the slandering and racist attack on Defendant, with "no evidence." Defendant responses follows:

I Andrew Sinclair the Defendant and owner of Earth Tea Extra Strength is competent enough to collect, review and analyze data from people who tried my product and make conclusions based on facts as a manufacturer.

Earth Tea Extra Strength was not formulated to be a covid cure, it was developed to be an immune support product. Covid-19 was used as a confirmation of successful immune support. The plaintiff accuses Defendant of trying to make money from the pandemic when during the pandemic highest peak 2020 Earth Tea Extra Strength was given away free in New York with the exchange for data. A matter of fact less than 1% of B4B Earth Tea LLC sales are for covid. (The plaintiff has this information.) Earth Tea Extra Strength was not marketed as an Covid-19 cure it was marketed as an Natural Immune support drink where the immune system can overcome covid. (That's an undeniable fact)

I think a conference would be more effective to handle this exchange between Defendant and the Plaintiff but I will try my best to summarized my responses and word it where it can be fully understood.

If the plaintiff had just took the time to ask questions instead of wrongfully judging Defendant this case could have been prevented. That's the reason for Defendant's systematic racism counterclaim where the plaintiff who is the government decided to jump to conclusions instead of asking for an explanation.

A. RESPONSE TO FACTUAL AND PROCEDURAL CONTEXT

The Plaintiff so far have not and cannot provided any facts to the court, because the plaintiff have not done any test, research or trials on the product in question. Thus all statements and arguments been submitted to the court are opinions. The FACTUAL AND PROCEDURAL CONTEXT submitted by the Plaintiff are all opinions and should be dismissed for failure of reasonable doubt.

Furthermore all accusations filed in the complaint are opinions which should disqualify the plaintiff's case against the Defendant. The plaintiff responses and arguments are misleading the court because they are not facts.

I the Defendant request that the plaintiff stop accusations without facts. This is constant racist attack by the plaintiff.

To make conclusions or judgments without testing or trying the Defendant's product is racism.

Earth tea extra strength a natural supplement have received hundreds of (feedbacks) from volunteers and customers who tried it. According to the **Dietary Supplement Health and Education Act of 1994 Public Law 103-417-103rd Congress**, natural supplements are legal in the United States of America. Earth tea extra strength is made from herb and other botanical **Section 201 (21 U.S.C. 321)(C)**. Natural supplement manufacturers are not required to submit data or prove claims to the FDA (plaintiff). Nevertheless I went beyond good manufacturing process and collected and analyzed data to ensure consumers were be genuinely advised.

I have provided numerous data to the plaintiff, data that Is not required by law but yet the plaintiff insisted they have not received any evidence. Here is a list of documents In the plaintiff's possession:

- 1. Live stream video experience along with dated test results showing Positive then Negative
- 2. 15 people clinical study (scientific proof)
- 3. My personal Internal notes recorded from feedbacks. (See feedbacks note below)
- 4. Sworn statements from witnesses about their experience.

Note: what are feedbacks?

People try Earth Tea Extra Strength mainly because they have an issue, Defendant asked everyone to give an update of the results. Most people would give day to day updates while other would give final results, this information is then recorded in Defendant's internal notes or memorized. I then analyze this data and give recommendations as a competent natural supplement manufacturer who give recommendations base on facts.

I have provided numerous proof that my posts are not false and misleading but the plaintiff refuses to accept my evidence and fail to present a single study or proof that shows otherwise.

My motion to dismiss was denied without asking the plaintiff to respond. In my motion to dismiss I specifically said that the plaintiff cannot produce a single evidence to backup

False advertising
Misleading advertising
False claims
Deception
Fraudulent claims

Even though the plaintiff was not asked to respond, I respect the court's decision and do not expect any bias from the Honorable Judges overseeing this process, but the fact still remains that the plaintiff doesn't not have such evidence and constantly respond with opinions.

For the above reason Defendant wishes to assert as an affirmative defense Statute of Limitation

B. DRUG CLAIMS RESPONSE

Defendant request that the plaintiff's claim that Earth Tea Extra Strength is a drug be dismissed for the following "specific reasons".

I. The FDA (plaintiff) purposely misguided Defendant with labeling instructions posted at www.fda.gov. As a do it yourself manufacturer, Defendant designed the product labels and marketing materials in house. Defendant went to the (FDA) plaintiff's website for instructions of required content for the product label. Defendant created the label based on information found on the plaintiff's website.

Defendant ask that the court please look at what Defendant saw and understand why my product was designed and sold without a disclaimer (Please see submitted file "EXHIBIT-FDA-label-Instructions.pdf") where Defendant ensure all required statements was added to the product label. Defendant was not advised or told that a disclaimer was required to legally sell the product as a natural supplement. This was purposely done by the FDA (plaintiff) who are aware of the Natural Supplement Law and are responsible to unbiased provide manufacturers with relevant compliant information. Defendant was not aware of adding a disclaimer statement to the product because it was purposely hidden by the plaintiff.

After this lawsuit was filed and Defendant searched online for the Natural supplement Act which is located at www.NIH.gov that was when Defendant found out that a disclaimer is what makes a product a natural supplement. Defendant request that the plaintiff (FDA) provides the url where they instruct or advise manufacturers that a disclaimer is "required" on natural supplements labeling. I also request that the FDA present evidence that the URL is dated at least between April 2020 to March 2022, date prior to Earth Tea sales and before this lawsuit was filed.

ADDITIONAL REASONS TO DENY DRUG CLAIM BY PLAINTIFF

- **II.** §5. Dietary Supplement Claims Chapter IV (21 U.S.C. 341 et seq.) Sec. 403B. (a) IN GENERAL.
- **III.** §7. Dietary Supplement Ingredient Labeling and Nutrition Information Labeling Section 403 (21 U.S.C. 343)
- **IV.** (b) Supplement Listing on Nutrition Labeling. Section 403(q)(5)(F) (21 U.S.C. 343(q)(5)(F))

None of the above sections (II, III, IV) of the law backs up Plaintiff claim that if a Natural supplement treats, cures or prevent an health condition its then considered a drug. I request that the plaintiff provide the section of the Dietary Supplement Act that supports such claim.

V. I deny the term claims and deny that my product was promoted as a covid cure or covid treatment. I Andrew Sinclair Defendant, marketed my product as an immune support drink. I ask that the plaintiff submit data, research, study, trial or any evidence that Earth Tea Extra Strength has no effect on the immune system.

VI. PUBLICATION ON THE FDA WEBSITE PRIOR TO THIS COMPLAINT.

(Please see file name EXHIBIT-CLAIMS.pdf for screenshots from the Plaintiff website that show natural supplements are used for health issues even though it is not "recommended" the term "not recommended does not mean illegal)

According to www.fda.gov

"Most people use natural supplements to treat many health conditions"

According to the **NIH** here's a list of few health conditions:

- 1. Asthma
- **2.** HIV
- 3. Arthritis
- 4. Breast Cancer
- 5. Autoimmune Disease

Therefore the claim that if a natural supplement helps overcome an issue it's a drug should be dismissed, because its false and misleading the court.

C. COUNTERCLAIM SUPPORT AND REQUEST TO DENY SOVEREIGN IMMUNITY

The plaintiffs response affirms my counterclaim that the plaintiff accusations are racist and the filed complaint is all based on opinions not facts.

I request that the court uphold my counterclaims and deny the plaintiffs sovereign immunity base on the following "facts"

- 1. The plaintiffs who is the FDA, FTC and DOJ bypassed guidelines put in place by the Dietary Supplement Health and Education Act of 1994 Public Law 103-417-103rd Congress. According to the complaint (March 20, 2022 Paragraph 50, 65) Defendant was Accused of "causing Americans to suffer substantial injuries" therefore Section 402 (21 U.S.C. 342)(1)(A) (2) of the Natural Supplement Act should have been implemented. That was not done.
- 2. At least One reason for filing this lawsuit is conflict of interest by the plaintiff who is the government (March 20, 2022 Complaint paragraph 34)
- 3. In addition the FDA purposely misguided Defendant with labeling instructions, where Defendant was not advised to add a disclaimer to the product's label. Knowing this requirement could have prevented this lawsuit, it's fair to believe that this was purposely hidden by the plaintiff who are trying to base this lawsuit on illegal drug sales.
- 4. Without research, test, trial or direct questions regarding Defendant product the plaintiff published slanderous publications to defame and damage Defendant personal image and brand. The plaintiff's published article was then re-published by news media outlets globally, where I Andrew Sinclair was labeled a deceiver and a scammer. This affirms racism by the Government where Defendant has been slandered without testing or research about the product in question. (**Submitted file name Exhibit-Slander.pdf**) shows an example of this attack and publications by the Plaintiff and various media outlets.
- 5. The plaintiff malicious use of process by filing this complaint with absolutely no evidence should also deny the plaintiffs sovereign immunity. In more than one instances the plaintiff caused Defendant to perform Acts that the Plaintiff claim is illegal.

for example: placing false orders, asking false questions to get responses to support this complaint. in addition plaintiff would make comments on post to mock Defendant online just to get Defendant to respond. Fake inquiries, where the plaintiff pretended to have

issues just to try and have Defendant say the word "yes I have the cure" many attempts was done but Defendant never uttered such statement. Finally fake reviews and feedbacks from plaintiff undercover.

6. Plaintiff abuse of power is additional reason to deny the plaintiffs sovereign immunity and monetary award should be granted to Defendant. The plaintiff requested that my fund raising campaigns be blocked, the plaintiff requested that my social media pages be blocked, the plaintiff requested that credit card processing companies close my account and requested that my contents are removed from search results. The above are all abuse of power actions done by the Plaintiff without a court order or lawsuit victory.

The above actions by the Plaintiff affected my sales and cause damages to my company that was growing globally. My distribution plans was halted and sales was denied because of illegal distribution charges threat by the Plaintiff. In 2023 when Defendant asked for additional time to gather funding, the plaintiff stated in their response that they would object to the extension to gather attorney funding if Defendant continued to update Defendant's' website. Therefore the plaintiff statement that Defendant was not told to stop selling the product is false.

Defendant global distribution plan was halted because companies would rather wait until the case is over than to risk been targeted. Consumers are also confused based on the publications by the Plaintiff calling Defendant a scammer. Therefore yes the plaintiff actions have cause pain and monetary suffering due to this case that was filed all based on opinions.

The plaintiff premeditated this case to wrongfully convict Defendant Andrew Sinclair. Defendant request that the court take in consideration that enforcing the law is not the same as purposely trying to wrongfully convict someone. Defendant ask that the plaintiff motion be denied in full.

D. ADDITIONAL REASONS. The Law

Defendant request that counterclaim be upheld because the plaintiff bypassed guidelines put in place by Congress to prevent racist prejudice cases by the Plaintiff. This abuse of power and failure to follow protocol should deny the plaintiff sovereign immunity.

- a. According to the Dietary Supplement Health and Education Act of 1994 Public Law 103-417-103rd Congress, passed by congress as of Today April 11, 2024 it is not illegal for manufacturers to make claims as long as it's not false or misleading. According to the Dietary Supplement Act (Section 403(r) (21 U.S.C. 343(r))) (the FDA who's responsibility is to keep manufacturers informed have not provided the process to alert the secretary if such claim is made as stated in the law)
- b. It is totally legal for Natural supplements manufacturers to make statements to cure, treat and prevent disease as long as such statements are not false or misleading according to Section 403(r) (21 U.S.C. 343(r)) of the Dietary Supplement Act. The plaintiff numerous times stated that Earth Tea is a drug because it's promoted as a cure or treatment. I would request that the plaintiff present the section of the law that supports such claim. I request that the plaintiff present evidence or the section of the law that specifically says if a Natural supplement cures, treat or prevent a disease or issue it is then converted to a drug.

F. CONCLUSION

The plaintiff publicly labeled Defendant a scam, fraud and deceiver without a single study, research or evidence therefore the plaintiff is racist. To judge anyone without proof or evidence is racism. I hope the court accepts this as a violation of the Dietary Supplement Health and Education Act of 1994 Public Law 103-417103rd Congress and an abuse of power, where the plaintiff publicly slandered

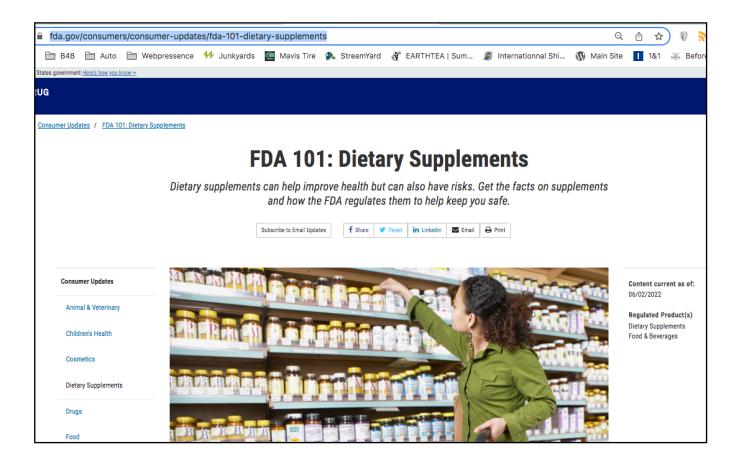
Defendant because the Plaintiff expects sovereign immunity. This lawsuit could have been avoided if the plaintiff had published the entire required label statements which includes adding a disclaimer to product labels. This lawsuit could have been avoided if the plaintiff had followed the rule set in place by the Dietary Supplement Health and Education Act of 1994Public Law 103-417103rd Congress. Where a dialog between Defendant and Plaintiff would be initiated, if there's a claim dispute.

Dated: April 11, 2024 Respectfully submitted,

FOR ANDREW MARTIN SINCLAIR / B4B EARTH TEA LLC

ANDREW SINCLAIR

/s/ Andrew Sinclair Andrew Sinclair 9703 Sutphin Blvd Unit 350008, Jamaica New York 11435 Telephone: (718) 635-2135 Email: ASinclairhg@gmail.com Below are screenshots of the FDA (plaintiff's website) where consumers are educated about dietary supplements. Even though it's not recommended by the FDA Dietary supplements are used to treat issues and verification is not required according to the Plaintiff, it's also not illegal to use Natural Supplement against health issues.



- Dietary supplement firms must report to FDA any serious adverse events that are reported to them by consumers or health care professionals.
- Dietary supplement manufacturers do not have to get the agency's approval before producing or selling these products.

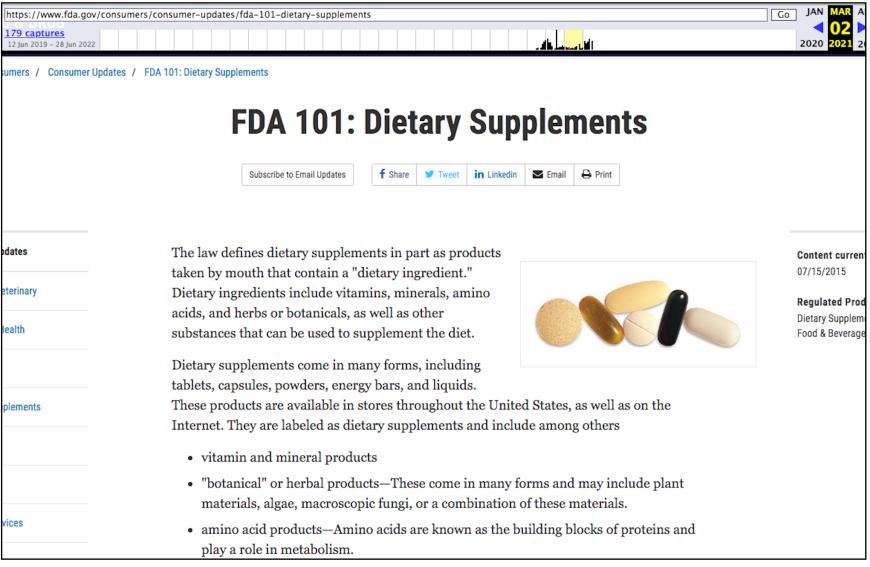
How Are Supplements Regulated?

You should know the following if you are considering using a dietary supplement.

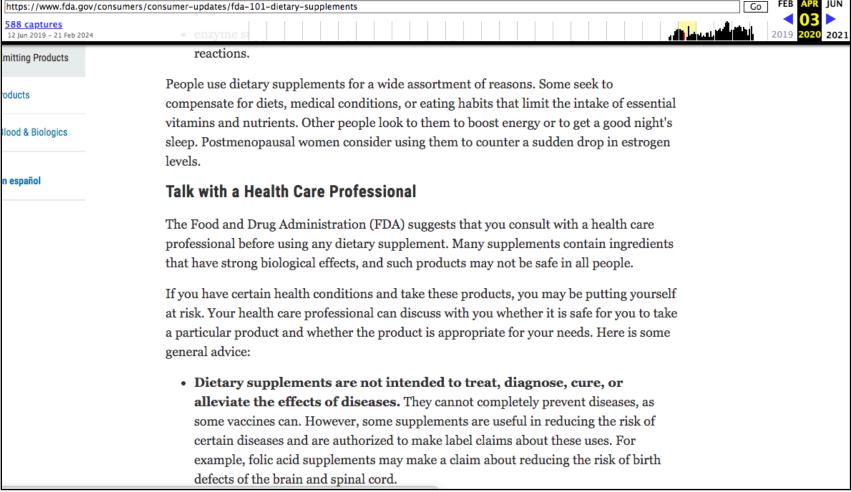
- Federal law requires that every dietary supplement be labeled as such, either with the
 term "dietary supplement" or with a term that substitutes a description of the
 product's dietary ingredient(s) for the word "dietary" (e.g., "herbal supplement" or
 "calcium supplement").
- Federal law does not require dietary supplements to be proven safe to FDA's satisfaction before they are marketed.
- For most claims made in the labeling of dietary supplements, the law does not require
 the manufacturer or seller to prove to FDA's satisfaction that the claim is accurate or
 truthful before it appears on the product.

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www.fda.gov Screenshots prior to lawsuit



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Dietary Supplements

Dietary supplements are regulated by the FDA as food, not as drugs. However, many dietary supplements contain ingredients that have strong biological effects which may conflict with a medicine you are taking or a medical condition you may have. Products containing hidden drugs are also sometimes falsely marketed as dietary supplements, putting consumers at even greater risk. For these reasons, it is important to consult with a health care professional before using any dietary supplement. Read these Consumer Updates to learn more.

How Are Supplements Regulated?

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 "calcium supplement").
- Federal law does not require dietary supplements to be proven safe to FDA's satisfaction before they are marketed.
- For most claims made in the labeling of dietary supplements, the law does not require
 the manufacturer or seller to prove to FDA's satisfaction that the claim is accurate or
 truthful before it appears on the product.

Are dietary supplements considered drugs?

Dietary supplements are regulated by the FDA as food, not as drugs. However, many dietary supplements contain ingredients that have strong biological effects which may conflict with a medicine you are taking or a medical condition you may have. Dec 21, 2021



fda.gov

https://www.fda.gov > consumers > consumer-updates

<u>Dietary Supplements - FDA</u>

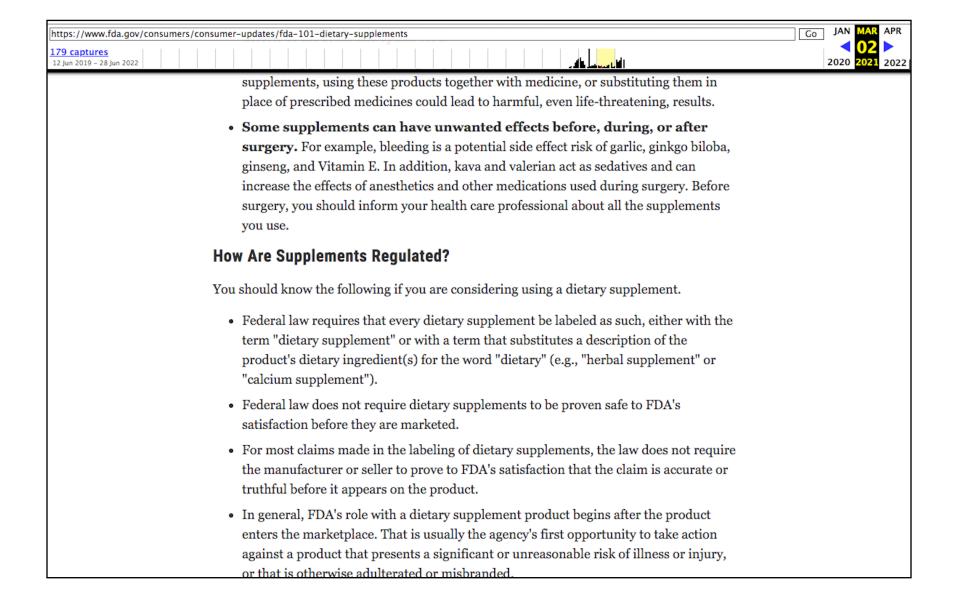
What is FDA's role in regulating dietary supplements versus the manufacturer's responsibility for marketing them?

In October 1994, the Dietary Supplement Health and Education Act (DSHEA) was signed into law by President Clinton. Before this time, dietary supplements were subject to the same regulatory requirements as were other foods. This new law, which amended the Federal Food, Drug, and Cosmetic Act, created a new regulatory framework for the safety and labeling of dietary supplements. Under DSHEA, a firm is responsible for determining that the dietary supplements it manufactures or distributes are safe and that any representations or claims made about them are substantiated by adequate evidence to show that they are not false or misleading. This means that dietary supplements do not need approval from FDA before they are marketed. Except in the case of a new dietary ingredient, where pre-market review for safety data and other information is required by law, a firm does not have to provide FDA with the evidence it relies on to substantiate safety or effectiveness before or after it markets its products. Also, manufacturers need to register themselves pursuant to the Bioterrorism Act with FDA before producing or selling supplements. In June, 2007, FDA published comprehensive regulations for Current Good Manufacturing Practices for those who manufacture, package or hold dietary supplement products. These regulations focus on practices that ensure the identity, purity, quality, strength and composition of dietary supplements.

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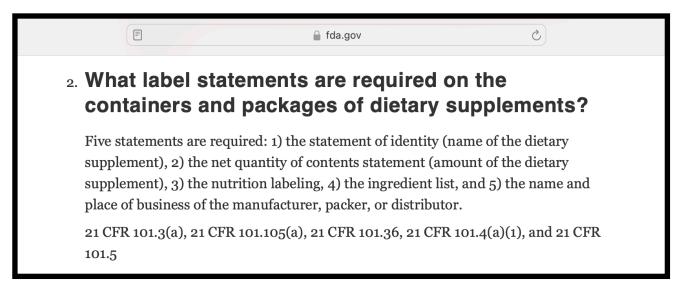
Date: April 11, 2024

www.fda.gov Screenshots prior to lawsuit



1. Information from www.fda.gov was used to create Earth Tea Extra Strength product label shown below. All required statement are shown below. There were no instructions to add a disclaimer by the plaintiff, who are responsible to give clear instructions to manufacturers.

SCREENSHOT FROM WWW.FDA.GOV / PRODUCT IMAGE BELOW







Justice Department Targets Deceptive Marketing of COVID 19 Herbal Teas

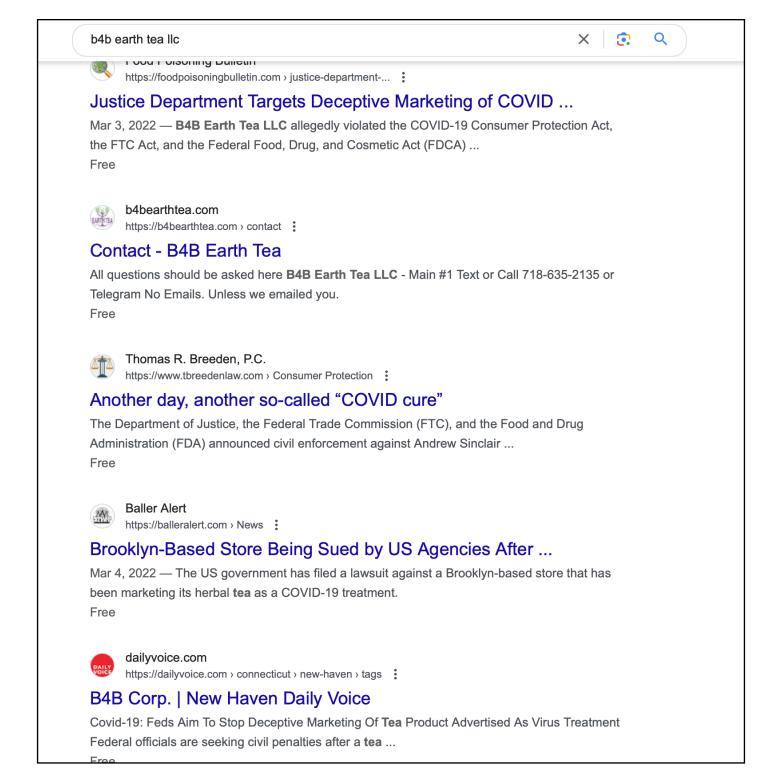
March 3, 2022 by News Desk

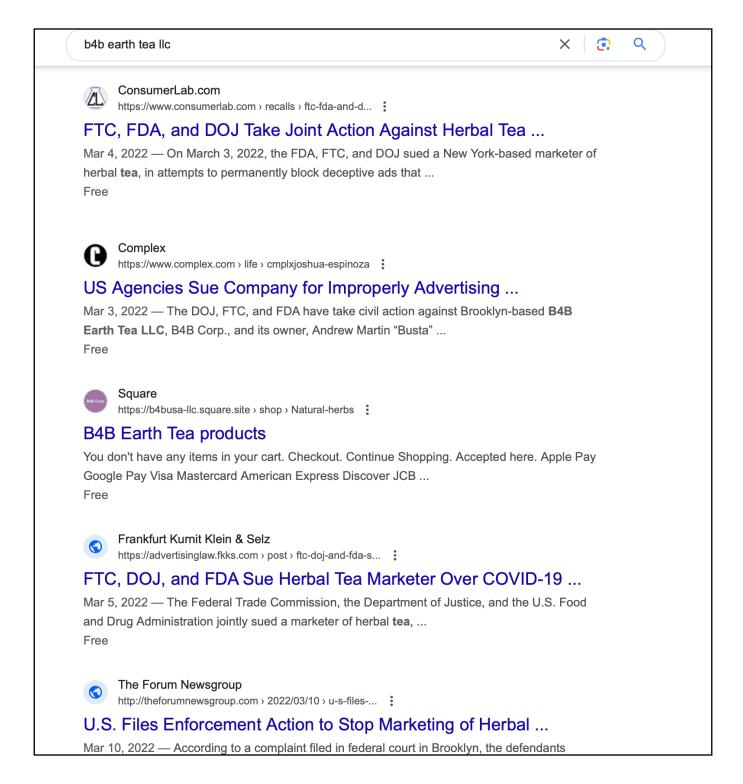


The U.S. Justice Department is targeting deceptive marketing practices of herbal tea products that are advertised as COVID 19 treatments. B4B Earth Tea LLC allegedly violated the COVID-19 Consumer Protection Act, the FTC Act, and the Federal Food, Drug, and Cosmetic Act (FDCA) according to the complaint. A complaint was filed in the U.S. District Court for the Eastern District of New York. The defendants allegedly advertised that their herbal tea product, Earth Tea, could prevent or treat COVID 19, without competent or reliable scientific evidence to support these claims. In addition, the defendants allegedly made deceptive statements about a scientific study to support their

unproven claims. The complaint also alleges that Earth Tea is an unapproved new drug that the defendants ... [Read more...]

Filed Under: Food Safety, News . Tagged With: COVID-19, U.S. Justice Department





https://www.miamiherald.com > news > article259069488

US agencies sue company for claims that its tea cures covid

Mar 4, 2022 — U.S. agencies including FDA and FTC are suing B4B Earth Tea for falsely advertising that their herbal tea could prevent or treat COVID-19. Missing: doj | Must include: doj

https://www.pacermonitor.com > public > case > United...

United States of America v. B4B Earth Tea LLC et al.

Mar 3, 2022 - United States of America v. B4B Earth Tea LLC et al (1:22-cv-01159), New York Eastern District Court, Filed: 03/03/2022 - PacerMonitor ...

https://www.techtrendsclub.com > doj-ftc-fda-sue-man-...

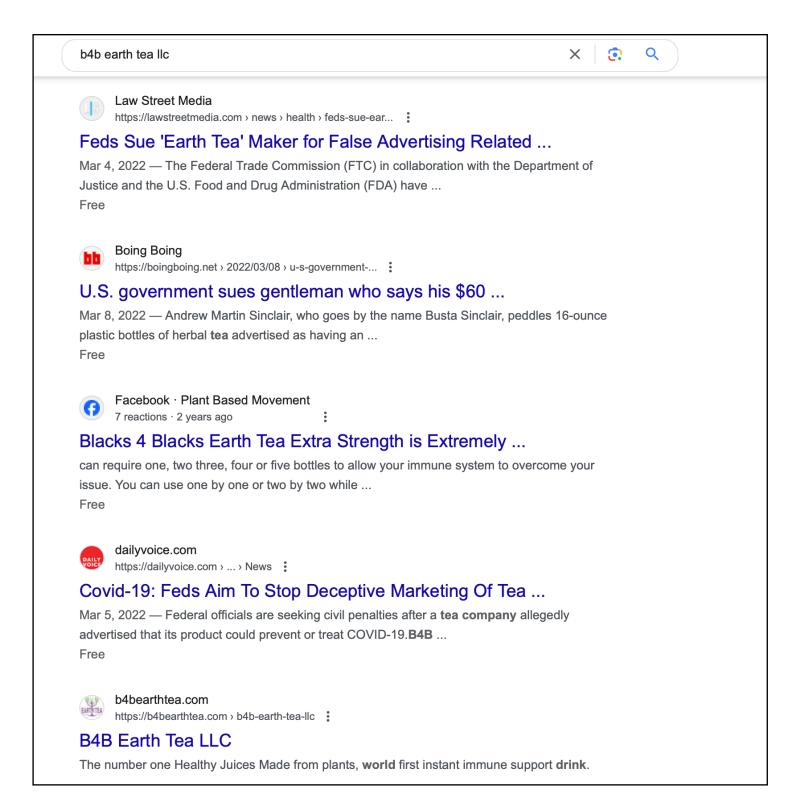
DOJ, FTC, FDA sue man who claims \$60 natural tea cures ...

Mar 8, 2022 - The Division of Justice, the Meals and Drug Administration, and the Federal Commerce Fee collectively filed a civil lawsuit towards a New York ...

https://aajtak.trem.media > science > 2022/03 > doj-ftc-fda...

DOJ, FTC, FDA sue man who claims \$60 herbal tea cures COVID ...

In the lawsuit filed Thursday, the federal agencies are seeking civil penalties and a permanent injunction barring Sinclair from selling Earth Tea or ...







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Exhibit-Slander.pdf Date: April 11, 2024

https://www.justice.gov > opa > file > download PDF

US v. B4B Earth Te - Department of Justice

Mar 3, 2022 — He also responded directly to a February 18, 2021 joint warning letter from the. FTC and FDA to **B4B Corp**. about false **or** unsubstantiated ...

https://www.justice.gov > ... > News

Justice Department Seeks to Stop Deceptive Marketing of ...

Mar 3, 2022 — The **Justice Department**, together with the Federal Trade Commission (FTC) are the U.S. Food and Drug Administration (FDA), today announced a ...

https://www.justice.gov > ... > News

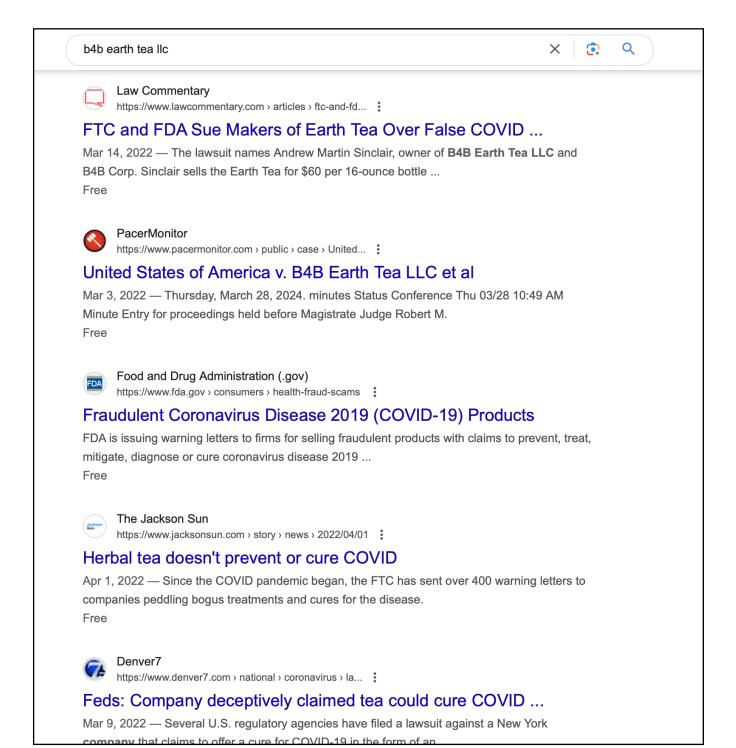
United States Files Enforcement Action to Stop Deceptive ...

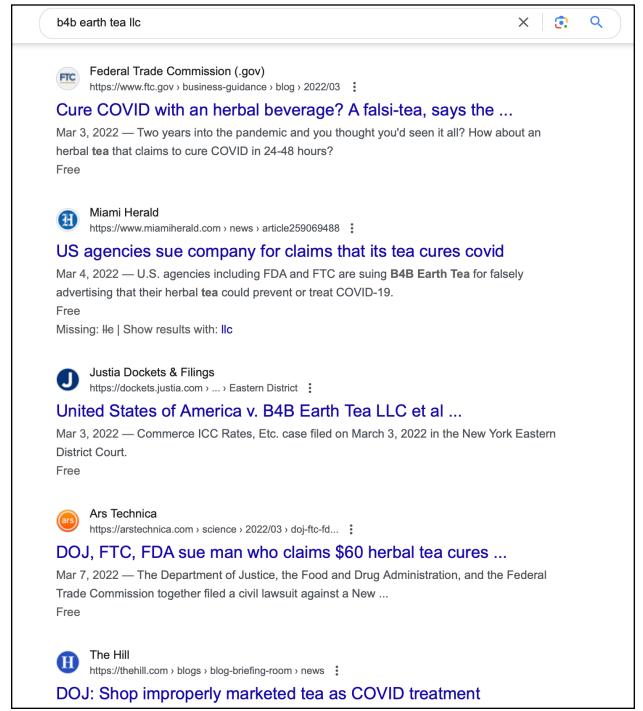
Mar 3, 2022 — According to a complaint filed in federal court in Brooklyn, the defendants advertised that their herbal tea product, Earth Tea, could prevent ...

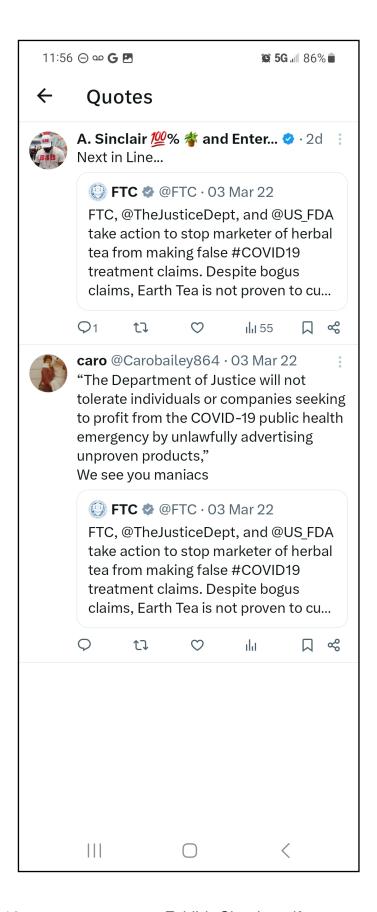
https://www.ftc.gov > news > press-releases > 2022/03 > ft...

FTC, DOJ, and FDA Take Action to Stop Marketer of Herbal ...

Mar 3, 2022 — The Federal Trade Commission, jointly with the Department of Justice and the U.S. Food and Drug Administration, have sued a New York-based ...









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